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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,496	03/28/2002	Akc Lignell	LIGN3005/REF	4529

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/31/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/088,496

Applicant(s)

LIGNELL ET AL.

Examiner

Susan Coe

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-25 is/are pending in the application.
- 4a) Of the above claim(s) 18-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 9-17 is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 9-25 are currently pending.

#### ***Election/Restrictions***

2. Applicant's election with traverse of Group I, claims 9-17 and Crohn's disease for species A in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the species of disease do not lack unity because they are joined by the single inventive concept of treating the diseases by regulating the immune response. This is not found persuasive because, as discussed below, the feature of regulating the immune response is considered to be inherent when the disease is treated; thus, each disease is considered to be distinct because the treatment of one disease would not necessarily make the other diseases obvious.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 18-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
4. Claims 9-17 are examined on the merits.

#### ***Claim Objections***

Claim 11 is objected to because of the following informalities: "rheumatoid" is misspelled as "reumatoid" and "tuberculosis" is misspelled as "tubercolosis." Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10, and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 9 is indefinite because it is not clear what degrees of Th1 cell mediated immune responses are considered encompassed by "excessive."

6. Claim 10 is indefinite because the Markush language is improper. This makes is unclear exactly what the members of the Markush group are. It is unclear if chronic viral and bacterial infections are one member or two separate members of the group.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,886,053.

US '053 teaches a method of treating Crohn's disease using astaxanthin (see column 1, line 25 and column 2, line 45). US '053 does not specifically teach that the treatment of Crohn's disease with astaxanthin has the same effects on T cells as those claimed by applicant. However,

these effects would have to be inherent in the method taught by US '053 because the reference teaches using the same composition to treat the same disease. If the method taught by the reference does not have these effects then applicant's invention would not function as claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 9 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,886,053 in view of US Pat. No. 5,744,502.

As stated above, US '053 is considered to teach the claimed method of treating Crohn's disease with astaxanthin; however, the reference does not specifically teach using astaxanthin from *Haematococcus* or that the astaxanthin is esterified with fatty acids.

US '502 teaches that astaxanthin derived from *Haematococcus* is esterified with fatty acids. US '502 teaches that this form of astaxanthin is preferable to other forms of astaxanthin because it is more efficiently absorbed by the patient and is more stable (see column 2, lines 41-54). Based on this disclosure, a person of ordinary skill in the art would understand the benefits of using the astaxanthin taught by US '502 in the method of treatment taught by US '053. Therefore, an artisan of ordinary skill would have been motivated to use astaxanthin esterified with fatty acids derived from *Haematococcus* to treat Crohn's disease.

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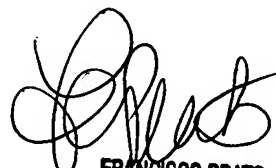
9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner  
March 26, 2003



FRANCISCO PRATS  
PRIMARY EXAMINER